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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,406

09/12/2003

Patrick P. Wu

ENDOS 64190

6647

24201 7590 01/26/2007

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,406	WU ET AL.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>111406, 101006, 100206</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

35 USC § 112 Sixth Paragraph

1. It is assumed that applicant has intended to invoke 112 sixth paragraph as per the means for language set forth in the claims.

a. In Claim 4, “means for evacuating air” is interpreted by the specification to be openings in the inner catheter or equivalents thereof.

b. In Claim 11, “means for preventing unintentional movement of the gear rack” is interpreted by the specification to be a locking arm or equivalents thereof

c. In claim 12 and 14, “means for allowing motion of the gear rack in only one direction” is interpreted by the specification to be a spring or equivalents thereof.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-4, 10-14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan III, et al. (USPN 5,968,052) in view of Failla et al. (USPN 5,501,654) further in view of Fitz (USPN 6, 146,415).**

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4. Sullivan discloses a system for delivering and deploying a medical device within a patient, the system comprising a delivery catheter including an inner catheter member (12) having a region for mounting the medical device (18) thereon and an outer restraining member (14) co-axially disposed over the inner catheter member and the medical device. The outer restraining member is adapted for axial movement with respect to the catheter. A control handle has the equivalent of a rotatable thumbwheel (68) connected a retraction mechanism and the inner catheter member has a proximal end (52) attached to the control handle and the outer restraining member having a proximal end attached to the retraction mechanism (32, 34). Actuation of the control handle causes linear movement of the retraction mechanism to proximally retract the outer restraining member sheath to uncover the medical device while the inner catheter member remains stationary. The equivalent of the thumbwheel rotates about an axis that is perpendicular to the linear movement of the retraction mechanism. The inner catheter member includes a guide wire lumen (35) extending from the proximal end of the inner catheter member to the distal end of the inner catheter member. A lock mechanism (48) prevents the retraction mechanism from moving proximally until the medical device is ready to be deployed. The device has means for evacuating air from the delivery catheter (24). With regard to claim 5, the device includes an outer sheath (introducer), which extends co-axially over a portion of the outer restraining member (Col 5, lines 43-45). The outer sheath is attachable to the entry point of the patient to provide a conduit for the delivery catheter. The outer sheath is removably attached to the control handle. The retraction mechanism includes a gear rack (84), which is

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slidable within a channel (90) formed in the control handle and a spur gear (70) which engages the gears of the gear rack. The equivalent of the thumbwheel (68) has an actuating gear, which mates with the spur gear (70) to cause the gear rack to move linearly within the channel when the equivalent of the thumbwheel is actuated. The system includes stop means (92) for preventing unintentional movement of the gear rack; for allowing motion of the gear rack in only one direction within the channel; for allowing motion of the gear rack in only one direction; and for allowing motion of the outer restraining member in only one direction. The stop mean is a spring having an edge that contacts the distal surface of the gears forming the gear rack to prevent distal movement of the gear rack.

5. Sullivan does not disclose that the actuating mechanism is a thumbwheel.

6. Failla et al. discloses a surgical device using a thumbwheel for actuating a gear to axially move a rack in order to axially move a distal portion of the medical device.

7. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a thumbwheel into the stent delivery device since Failla offers it as an alternate actuation mechanism. The gear and rack mechanism of Failla are analogous with the gear and rack mechanism of Sullivan. Failla merely offers an equivalent structure for initiating the actuation of the gear and rack mechanism.

8. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan III, et al. (USPN 5,968,052) in view of Failla et al. (USPN 5,501,654) further in view of Fitz (USPN 6, 146,415).

9. Sullivan in view of Failla disclose the device as stated above. Sullivan in view of Failla does not disclose that the outer sheath is attached to the control handle to prevent the inner catheter member from moving distally when the outer restraining member is retracted.

10. Fitz discloses a stent delivery system that comprises an inner catheter (10), a restraining sheath (16) and a guide catheter analogous to that which is disclosed by Sullivan. Fitz further discloses a coupling member (40) wherein the proximal end of the delivery catheter is attached to the guide catheter to provide a means to fix the position of the catheter handle with respect to the guide catheter (Col 6, line 56-62). Fitz states that this feature is an improvement to stent delivery catheters because it prevents unwanted movement of the device during delivery and provides grater accuracy of stent placement.

11. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the coupling member into the stent delivery device to enhance the function of the device by ensuring accurate delivery of the stent. Fitz provides the motivation which is well within the scope of the invention. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

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12. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Failla further in view of Fitz as applied to claim 5 above, and further in view of Kratoska et al. (USPN 6,183,443)

13. Sullivan in view of Failla discloses the instant invention substantially as claimed as stated above except for "the outer sheath is attached to a strain relief member, which is removably attached".

14. Kratoska discloses an introducer sheath having a proximal end attached to a strain relief member. The introducer of Kratoska is a separate entity from the device that is being inserted into it just as in Sullivan in view of Failla. The introducer has a distal portion that has a smaller inner diameter than a proximal portion of the sheath.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a strain relief into the introducer since it is well known in the art to use a strain relief as evidenced by Kratoska to reduce buckling or kinking.

16. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Failla further in view of Fitz as applied to claim 7 above, and further in view of Lowery et al (USPN 4,624,243).

17. Sullivan in view of Failla discloses the instant invention substantially as claimed as stated above except for "the strain relief having a channel for receiving a tab like member of the control handle".

18. Lowery discloses that it is old and well known in the art to use a threaded connection between an introducer and a medical device. The spaces between the

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threads of the introducer are analogous with the channel of the strain relief and the projecting threads of the medical device are analogous with the taps on the control handle.

19. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate threads into the introducer and the medical device since it is old and well known in the art. Furthermore it provides the advantage of stabilizing the device while performing the medical procedure.

Response to Arguments

20. Applicant's arguments, see bottom paragraph of page 9- page 10, filed 11/08/06, with respect to claim 5 have been fully considered and are persuasive. The rejection of 08/08/06 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly applied prior art.

21. Applicant's arguments filed 11/08/09 have been fully considered but they are not persuasive. Applicant states that the Sullivan device would not achieve the basic structure of the claims if the Failla feature of the thumbwheel were incorporated. Examiner respectfully disagrees. The basic structure of the Sullivan device is in fact similar to the instant invention. The Sullivan device has a gear rack, a spur gear and a gear (68) that is equivalent to the thumbwheel. To incorporate a thumbwheel in place of the actuating handle may require other modifications that just adding a thumbwheel, such as the removal of part (82) which requires the back and forth motion referenced by

the applicant. In other words the spur gear would directly engage the gear rack replicating the invention of the instant invention as well as the thumbwheel gear and rack mechanism of Failla. It is a modification that is well within the skill of the ordinary artisan. It is irrelevant that the actuating mechanism in Failla does not move an outer sheath. It is merely the thumbwheel and gear rack for which Failla is relied on.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

1/19/57.